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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,438	GUTTMAN ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *9,10,14 and 20-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-13 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7142003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' responsive amendment filed 07 July 2004 in response to Office Action of 1 June 2004 is acknowledged and entered.

2. Applicants' filing of sequence Listing in paper (1 page) and computer readable form (i.e., CRF) along with the statement that Sequence Listing and Computer Readable Copy are the same filed 07 July 2004 in response to Office Action of 1 June 2004 is also acknowledged and entered.

CLAIMS STATUS

3. Claims 1-33 are pending.

Restriction/Election

4. Applicants' election without traverse of Group I, Claims 1-8 and 11-19 filed 07 July 2004 in response to Office Action of 1 June 2004 is acknowledged and entered. Applicant's species election of: a) adjust diffusion rate, b) enzymes, c) restriction enzymes and d) nucleic acid for prosecution of this application in response to Office Action cited *supra* is also acknowledged.

Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 9-10, 14 and 20-33 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in response to this Office action to expedite prosecution.

5. Claims 1-8, 11-13 and 15-19 are examined on merits.

Information Disclosure Statement

6. Applicants' Information Disclosure (i.e., IDS) filed 14 July 2003 has been made of record and considered.

Objection to Information Disclosure Statement

7. The information disclosure statement filed 14 July 2004 is deficient. Please furnish a complete copy pf the reference, "Guttman, LC/GC Magazine, 17:1020-1026, 1999, "Automated DNA Fragment Analysis by High Performance Ultra-thin Layer Agarose-gel Electrophoresis". In its present form, the cited reference does not include date of publication or any of the citation data of said reference.

Priority

8. Applicants' claim for domestic priority under 35 U.S.C. §120 is acknowledged.

Objection To Specification

9. The specification is objected to because the first page of specification, in its present form does not properly cite the application priority data. It is requested that the first line of the first page of the specification indicate that the instant application is a 371 of the earlier filed PCT application, as follows.

This application claims priority to U.S. Provisional Application Serial Number 60/367, 378 arising from --- Non-Provisional U.S. Application Serial No., filed _____, which claims priority to _____ application Serial No. _____, filed _____.

Claims Objection

10. Claims 3, 6, 8, 11-13 and 16-19 are objected to because at Line one of the each of the cited Claims before the word "wherein" a --, -- should be inserted. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 1-8, 11-13 and 15-19 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- The recitation "nanoporous" in Claims 1, 5-6, 11 and 15 renders those claims vague, unclear and indefinite, because the metes and bounds for said term are not defined in the claim language. Applicant should clearly define all the parameters for the term, "nanoporous".

- Term "includes" renders Claims 3,6, 8, 11-13 and 16-19 vague and indefinite because it is not clear whether said term is open, like the conventional term "comprising" or whether the term excludes other ingredients, like the term "consisting of Examiner suggests that the applicants use the transitional phrase—"comprises".

- The recitation "kinetic characteristic" renders claim 7 vague, unclear and indefinite, because the metes and bounds for said term are not defined in the claim language. Applicant should clearly define all the parameters for the term, "kinetic characteristic".

All other claims depend directly from the rejected claims (e.g., Claim 14) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

14. Claims 1-8 and 15 are rejected under 35 U.S.C. §102(b) as anticipated by Mauck (U.S. patent 5,032,504).

Claims recite a method to produce a product by contacting a first reactant with a second reactant through a nanoporous structure, wherein first component is added to the nanoporous structure and after a certain waiting time the second component is mixed in and the two components are incubated together. The kinetic characteristics/diffusion rate of the component is enhanced and a third component is also contacted with the nanoporous membrane.

Mauck teaches a method to contact a chlamydial or gonococcal antigen extracted from a sample with a surfactant coated polyamide microporous membrane. Said membrane has an average pore size of 1 μm to 10 μm. Ten minutes subsequent to contacting said membrane with said antigen sample, the membrane is contacted with a chlamydial or gonococcal antibody the mixture resulting in an immunological complex. Said complex is determined/assayed on said membrane with appropriate detection means thereby indicating presence/absence of Chlamydia or gonococci in the sample from where said antigen containing extract was prepared. The assay is rapid because in contrast to technology/methods/assays known prior to Mauck's teachings, Mauck's assay is completed in < 30 minutes at room temperature (Column 2, Lines 29-68). Note that as the membrane is coated with a surfactant, there is actually a third component aside from the two reactants (i.e., antigen and antibody) that produce the product, i.e. immunological complex. The waiting period before determining the complex and after mixing the antigen and antibody is the incubation period and since the reaction occurs rapidly because of the coating the diffusion rates for both antigen and antibody into the polyamide membrane is enhanced that inherently is an adjustment of the reaction kinetic characteristics.

Furthermore, as the applicants have not defined metes and bounds for a nanoporous structure, a membrane having average pore size of 1 μm to 10 μm has an average pore size of 1,000 nm to 10,000 nm.

Therefore, the reference is deemed to anticipate the cited claims.

15. Claims 1, 11-13 and 15-18 are rejected under 35 U.S.C. §102(b) as anticipated by Jacobson et al. (Analytical Chemistry, 1996, Volume 68, pages 720-723) with evidence provided by Guttman et al (U.S. Patent 5,370,777).

Claims recite a method to produce a product by contacting a first reactant with a second reactant through a nanoporous structure, wherein first component is an enzyme, the second component a nucleic acid and product is a nucleic acid fragment.

Jacobson et al. teach a method, wherein the plasmid pBR322 (i.e., DNA) is chopped in a reaction buffer incubated at room temperature (i.e., 20° C) with a restriction enzyme in a chip reaction chamber comprising polyacrylamide and the products are subsequently separated in the separating column of the chip. The polyacrylamide is immobilized to the chip so it is in form of a membrane (Page 721, Column 1, Lines 20-22 under Figure 1;Column 2, Lines 1-23 under Figure 3 and Figure 3) and depending upon the concentration, the polyacrylamide may have a stable porosity of on an average of 80 nm (See Guttman et al., Column 8, Line29).

Therefore, the reference is deemed to anticipate the cited claims.

In this rejection under 35 U.S.C. §102(b Guttman et al (U.S. Patent 5,370,777) is cited to merely support that the polyacrylamide gel has an average porosity of 80 nm, and said reference is not cited as a prior art reference.

Claim Rejections - 35 U.S.C. § 103

16. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

18. Claims 1-8, 11-13 and 15-19 are rejected under 35 U.S.C. § 103 (a) as obvious over by Mauck (U.S. patent 5,032,504) in view of Jacobson et al. (Analytical Chemistry, 1996, Volume 68, pages 720-723) with evidence provided by Guttman et al (U.S. Patent 5,370,777) and Guttman et al (Electrophoresis, 2000, Volume 21, Pages 3952-3964).

Claims recite a method to produce a product by contacting a first reactant with a second reactant through a nanoporous structure, wherein first component is added to the nanoporous structure and after a certain waiting time the second component is mixed in and the two components are incubated together. The kinetic characteristics/diffusion rate of the component is enhanced and a third component is also contacted with the nanoporous membrane. Claims further recite a method to produce a product, wherein first component is an enzyme, the second component a nucleic acid and product is a nucleic acid fragment.

Teachings from Mauck and Jacobson et al. with evidence provided by Guttman et al. (U.S. Patent) have already been discussed *supra*. Their teachings, however, do not disclose that product of reacting an enzyme and a nucleic acid is an amplified nucleic acid fragment, wherein incubation is carried out at a series of temperature changes to achieve amplification.

Guttman et al. (Electrophoresis) reviewing advances in ultra thin-layer gel electrophoresis of DNA beneficially teach an analysis of PCR-generated samples genotyping and reaction of components with a nanoporous material. Since the samples were produced through PCR, Guttman et al., intrinsically teach that the incubation was carried out at a series of temperature changes to achieve amplification.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Mauck according to teachings from Jacobson et al. with evidence provided by Guttman et al. and Guttman et al. (Electrophoresis) to obtain a method to produce a product by contacting a first reactant with a second reactant through a nanoporous structure, wherein first component is added to the nanoporous structure and after a certain waiting time the second component is mixed in and the two components are incubated together. In said reaction the first component is an antigen/ nucleic acid, the second component an antibody/ restriction nuclease and the product an immunological complex/ amplified or a non-amplified nucleic acid fragment. The kinetic characteristics/diffusion rate of the components is enhanced and a third component is also contacted with the nanoporous membrane, because Mauck, Jacobson et al. and Guttman et al. teach contacting two

different reactants and a third component through a nanoporous size membrane to produce a product, Jacobson et al. with evidence from Guttman et al. (U.S. Patent) remedy the deficiency of a nucleic acid and a nuclease enzyme as well as the membrane nanopore size (i.e., 80 nm) in teachings from Mauck, while Guttman et al. (Electrophoresis) remedy the deficiency of a product being an amplified DNA fragment in Mauck's teachings.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Mauck with those from Jacobson et al. with evidence provided by Guttman et al. (U.S. Patent) and those from Guttman et al. (Electrophoresis) to obtain a method to produce a product by contacting a first reactant with a second reactant through a nanoporous structure membrane, wherein first component is an antigen/ nucleic acid, the second component an antibody/ restriction nuclease and the product an immunological complex/ amplified or a non-amplified nucleic acid fragment. Jacobson et al. remedy the deficiency of a nucleic acid and a nuclease enzyme in teachings from Mauck, while Guttman et al. (Electrophoresis) remedy the deficiency of a product being an amplified DNA fragment in Mauck's teachings.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

19. No Claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Art Unit 1651
(571) 272-0923

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

September 29, 2004